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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,027	11/12/2003	Shibo Jiang	#706-A-US	6196

7590 11/28/2006

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EXAMINER	
POWERS, FIONA	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,027	JIANG ET AL.	
	Examiner	Art Unit	
	Fiona T. Powers	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *65* is/are allowed.

6)☒ Claim(s) *39-58,63,64 and 66-68* is/are rejected.

7)☒ Claim(s) *59-62* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Receipt is acknowledged of the amendment filed September 20, 2006, which has been entered in the file.

Claim 40 and 58 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 40 is not a further limitation of claim 30 because the R groups can be "another acidic group" which includes acidic groups not included in claim 39 (for example PO_3H_2).

Claim 58 is not a further limitation of claim 39 because it is drawn to "the pharmaceutical composition" which is broader than claim 39, which is drawn to "an antiviral pharmaceutical composition".

Claims 59 to 64 and 67 are objected to because of the following informalities: claims 59, 61 and 63 refer to "formula I" but the formula does not appear in the claims. In claim 61, "thereof" should be deleted. Claim 67 refers to an antiviral pharmaceutical composition of claim 65. However, claim 65 is drawn to a compound of the formula I. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39 to 58, 63, 64 and 66 to 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and

8. the level of skill in the art.

See In re Wands, 8 USPQ2d 1400.

The nature of the invention is an antiviral pharmaceutical composition and a method for the preventing manifestation of AIDS.

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases and by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming an antiviral pharmaceutical composition and a method for the preventing manifestation of AIDS.

The state of the prior art is that antiviral therapy remains highly unpredictable. The phrase "an antiviral pharmaceutical composition" implies that the compounds can be used against any viral disease such as the common cold, hepatitis virus etc. The various types of viral diseases have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol.

There have been no structurally similar compounds found which prevent manifestation of AIDS. Inosine pranobex was found by Pedersen et al. to prevent AIDS (Pedersen et al., New England Journal of Medicine, 322(25), 1757-1763, June 21, 1990). However, Kweder et al. state "The lack of corroborating evidence of efficacy based on other clinical or laboratory markers of disease progression, combined with the absence of a basic understanding of the pharmacology and mechanism of action of inosine pranobex, makes a confirmatory study mandatory before claims of efficacy can be accepted by the scientific and medical community or by regulatory agencies such as the FDA" (Kweder et al., New England Journal of Medicine, 322(25), 1807-1809, June 21, 1990).

The only direction or guidance present in the instant specification is data on the inhibition of HIV-1 by NB-2 and NB-64. There are no working examples present for the use of the

compounds for the treatment of any other viral disease or for preventing manifestation of AIDS.

The breadth of the claims is an antiviral pharmaceutical composition and a method for the preventing manifestation of AIDS.

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what viral diseases would be benefited (treated) by and would then have to determine which of the claimed compounds would provide treatment of which disease, if any.

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the instant claims as antiviral pharmaceutical composition and a method for preventing manifestation of AIDS. As a result necessitating one of skill to perform an exhaustive search for which diseases can be

treated by what compounds of the instant claims in order to practice the claimed invention.

Genetech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher discussed above, to practice the claimed invention herein, one of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39 to 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (Journal of Medicinal Chemistry, 21(11), 1100-1104, 1978), of record.

The reference discloses pharmaceutical compositions comprising compounds of the formula I where X is C or N and R_1 to R_9 are selected from H, COOH and OH. Note Compound Nos. 4, 5, 7 and 10 to 12 of Table I on page 1101. Because the reference

discloses pharmaceutical compositions comprising compounds encompassed by formula I, it would be inherent that the compositions would also be antiviral pharmaceutical compositions.

To overcome the 112 rejection and avoid the prior art claims 39 to 58, 63 and 64 should be cancelled, claim 66 should be amended by deleting "antiviral", claim 67 should be amended by deleting "preventing manifestation of AIDS" and inserting -treatment of AIDS-.

Claims 59 to 62 would be allowable if amended to overcome the objection identified above.

Claim 65 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fiona T. Powers
Primary Examiner
Art Unit 1626

ftp
November 21, 2006